

Summary

Currently, black and white copy is still most commonly used today and it is fully appropriate for the vast majority of labeling and packaging for prescription drug products. However, there are some unique considerations arising in the context of patient-directed labeling and packaging for certain prescription drug products that merit the use of color in labeling. Color is now and should continue to be one "tool in the toolbox" to facilitate informative communication between one party (in this case, a prescription drug manufacturer) and the audience (in this case, health care professionals and patients/consumers). CDER should continue its regulatory discretion, under current regulations, to approve packaging and labeling, with color, in appropriate situations.

This submission is provided in electronic format according to the instructions provided at <http://www.accessdata.fda.gov/scripts/oc/dockets/commentdocket.cfm?AGENCY=FDA>.

Please contact me at (919) 483-6405 if you require clarification or have questions about these comments. Thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Anne N. Stokley". The signature is fluid and cursive, with a large loop at the end of the last name.

Anne N. Stokley, M.S.P.H.
Director, Policy, Intelligence & Education
US Regulatory Affairs